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Using Mock Recall Data to Measure Continuous Quality Improvement

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Introduction

Continuous quality improvement is essential to firms who wish to function within a global business environment. Strategic quality improvement is often facilitated through a formalized quality management system (West & Cianfrani, 2004). Quality management systems have been used for many years in industries such as manufacturing and health care to improve efficiencies and maintain high levels of customer satisfaction (Deming, 2000; Bowersox et al., 2007), but their use in processing industries such as food and agriculture is a more recent trend (Hurburgh & Lawrence, 2003). These systems provide a way for firms to focus on customer requirements and tighten their supply chains by clearly defining and controlling their operations and processes (West & Cianfrani, 2004).

The development of a quality management program has many steps and planning may require twelve months or longer. Implementation may take several additional months (Hurburgh, 2002). Because of the many resources needed to develop and implement a quality management system, an assessment of the program's efficiency is necessary. An effective evaluation plan is important for two reasons: first, to determine the effectiveness of the implementation and second, to facilitate continuous improvement within the organization (Fitzpatrick et al., 2004; Laux & Hurburgh, 2008).

An impartial third party audit provides validation needed for quality management system certification or other documentation of strategic quality measures (Hurburgh, 2002). Audits occur infrequently and are usually performed by outside personnel. The need exists for a quicker, internal, and more frequent way to evaluate a quality management system. This paper will discuss mock recall as a possible tool to evaluate a quality management system for a processing firm more quickly and frequently using internal personnel.

Quality Management Systems in Processing Firms

Process controls and verification of standards inherent to quality management systems are not new to other industries, but these ideas are a major departure from business as usual for commodity-based food and agricultural firms (Hurburgh, 2002). Preliminary research has illustrated several benefits for agricultural and food processing facilities which implement quality management systems. Research completed by Laux (2007) illustrated the following benefits for the agricultural processor studied:

- Improved operating efficiency resulting in process cost savings
- Increased ability to meet customer product requirements
- Provided tighter food security controls

Quality management systems have the potential to provide greater inventory and process control. To take advantage of this, some type of an evaluation must be used on a regular basis. To assist in this effort, continuous improvement tasks are coordinated by personnel to keep the quality system relevant and meaningful (Taormina & Brewer, 2002). Data collected from daily operational tasks allows the firm to measure the program's success as well as provide data for future decision-making.

Recalls in the Processing Industry

The goal of manufacturers and processors is to prevent recalls. Although recalls are unpredictable, it is in the best interest of the company to manage any recall that does occur so that it runs as smoothly as possible (Kaletunc & Ozadali, 2002). To facilitate an organized and well-prepared recall, a documented recall program should be developed by the firm before a recall occurs (Keener, 2007). A recall plan is also an important component of inventory and process control, and can also address food traceability concerns (Laux & Hurburgh, 2008).

A written recall plan includes several parts; each component tested for effectiveness through a mock recall exercise. A mock recall is designed to occur randomly and is typically unannounced (Keener, 2007; Mosher & Brumm, 2008). The goal of a mock recall exercise is to test the recall procedure(s) by evaluating the firm's ability to locate and isolate all of its product(s). The exercise may be timed and may also employ a third party to evaluate both the recall procedures and the firm's performance on the mock recall (Keener, 2007).

Legislative Requirements

Mock recalls are based on requirements of the U.S. Public Health Security and Bioterrorism preparedness and Response Act of 2002 (Food and Drug Administration, 2002). This legislation requires all companies involved in the food and feed industry to register with the Food and Drug Administration (FDA). Section 306 of the 2002 Act requires all companies to register and keep records identifying immediately previous sources and the immediate subsequent recipients of materials used in food and feed (Food and Drug Administration, 2002). Companies have used mock recalls before but the legal requirements of FDA traceability have prompted many organizations to develop and employ mock recall exercises for the first time (Foukes, 2005).

To facilitate timely information release for potential recall, FDA requires a company to produce the records within 24 hours of the initial request (Food and Drug Administration, 2002). However, the legislation only requires that the records are presented within 24 hours. The agency does not specify the veracity of the data collected. Records may not necessarily be accurate or complete – but if they are produced within the required time frame, they meet the legislative regulation. To help firms prepare, mock recalls are often instituted within a quality management system (Laux, 2007). A mock recall in a quality management system measures data accuracy since a thorough analysis may be performed during and after the exercise, unlike an actual recall event.

Conducting the Mock Recall

To conduct a mock recall, the facility manager randomly chooses a product and announces that the product in question must be identified and isolated from the remainder of the goods. In the case of a mock recall, the product which cannot be verified as safe may remain in storage, in an authentic recall, all products which cannot be confirmed as safe would be destroyed.

The frequency of the mock recall exercise may vary, depending on two factors. First, the maturity of the quality management program and recall plan and second, past performance on previous mock recall exercises are also noted (Foukes, 2005). A mature quality management system with a recall plan may only conduct a mock recall drill once or twice annually. An organization with a new quality management system and recall program may need additional drills. Past performance should also impact the frequency of mock recall exercises. If the firm performs poorly on a series of mock recall exercises, additional practice with recall procedures may be warranted (Foukes, 2005).

Several recall scenarios may be tested by a mock recall exercise. A forward recall attempts to locate product sent from a supplier to an unknown customer or firm. The forward recall is often used as part of Good Business Practices (GMPs); it is not typical of most recalls requested by the FDA. More frequent is the backward recall: a contaminated product must be traced from the customer to the supplier and originating manufacturer (Laux & Hurburgh, 2008).



When a firm has accurate records of suppliers and subsequent customers, a recall of a single ingredient is easily handled. However, a more challenging situation is a recall of a finished product, where multiple contaminated ingredient are unknown and accompanying lot numbers of all raw materials must identified and located. This type of scenario may severely test the 24 hour time limit (Foukes, 2005).

Performance Indicators

Several indicators may be measured during a mock recall exercise. Two events are tested for effectiveness: the ability to trace products or ingredients and how well the recall team communicates and functions during a recall scenario (Foukes, 2005). Additional information gathered during a mock recall may include the number of hours required to provide the recall information required by the FDA and the potential financial loss from suspect product which cannot be identified or located (Mosher & Brumm, 2008).

Methodology

Data for this evaluation was taken from summaries of a series of mock recall exercises completed in 2006, 2007, and 2008. An example of a mock recall procedure is shown in Appendix A.

Several research questions guided the collection and analysis of mock recall data.

1. Can mock recall data be used to evaluate the yearly performance and compliance of processing sites per the 24 hour requirement of the Bioterrorism Act of 2002?
2. How can mock recall data be used to measure effectiveness of recall procedures?
3. Can mock recalls provide a rapid method of evaluating continuous quality improvements in organizations using quality management systems?

Results

This project examined a quality management system that was implemented within an agricultural processing facility. Two performance indicators are measured in a mock recall: the time in hours needed to produce the required records and the amount of product which would be destroyed if the source or recipient could not be verified. The second of these indicators could be used in a second tool used to measure the effectiveness of the quality management system. This tool is known as the traceability index and it is described in greater detail by Laux and Hurburgh (2008).

Using SPSS version 14, several data sets were analyzed. The first set was the number of hours needed to produce all required records. The number of hours was defined by the time the mock recall was returned to management by email subtracted from the time it was delivered. The mean number of hours it took the processing facilities to run the mock recall exercises each year were measured. A significance test compared the group means of each year's data and a confidence interval was constructed to determine the magnitude of the difference among years within a 95 percent confidence level (Bonett & Wright, 2009).

The second piece of data was an examination of the traceability index. This measure assigns a quantitative measurement of the source(s) of the current inventory of grain held by the facility and determines the effectiveness of the mock recall. Table 1 displays the mean number of hours and the mean traceability index values of each year and 95% confidence intervals for each mean value.

Table 1. Means and Confidence Intervals for Recall Hours and Traceability Index Values

Measure	Year	Mean	95% Confidence Interval Bounds
Recall Hours	¹ 2006	11.75	Lower 5.12 Upper 18.37
Recall Hours	² 2007	18.01	Lower 12.08 Upper 23.94
Recall Hours	³ 2008	5.28	Lower 1.76 Upper 8.81
Traceability Index	¹ 2006	417.35	Lower 110.22 Upper 724.47
Traceability Index	² 2007	443.46	Lower 296.30 Upper 590.62
Traceability Index	³ 2008	320.36	Lower 54.53 Upper 586.19

¹n = 9; ²n = 16; ³n = 18

Significance tests were performed to compare the recall hours needed and the traceability index values each calendar year. Table 2 illustrates these results.

Table 2. T-Tests of Differences in Group Means

Measure	Years Compared	Mean	Significance
Recall Hours	¹ 2006 ² 2007	8.55 16.63	0.296
Recall Hours	2007 ³ 2008	16.63 4.52	0.010*
Recall Hours	2006 2008	8.55 4.52	0.013*
Traceability Index	⁴ 2006 ⁵ 2007	386.20 443.46	0.438
Traceability Index	2007 ⁶ 2008	443.46 277.47	0.640
Traceability Index	2006 2008	386.20 277.47	0.921

* Significant at p-value of 0.05; ¹n = 21; ²n = 19; ³n = 23; ⁴n = 10; ⁵n = 16; ⁶n = 27

Discussion and Implications

The measurement of the number of hours needed to gather information for a mock recall exercise showed interesting patterns. From 2006 to 2007, an increase in the number of hours needed for the firm to provide the required information from a mock recall was noted, but not significant. However, great improvement was documented in 2008, confirmed by significant differences in the number of hours needed in 2008 with those in 2006 and 2007. The relatively narrow confidence interval in 2008 also provides data which illustrate improvement in the quality management system.

Basic data from mock recall exercises can be used as a very rough measure of the success and yearly improvements of a quality management system, the traceability index provides data on information accuracy. The effectiveness of the recall information is what will determine the effectiveness of an actual recall event (Foukes, 2005). Thus, the traceability index provides an important evaluative component. Traceability indices are high with no significant improvement from year to year.

Large confidence interval boundaries also indicate a wide distribution of values, leading to the conclusion that while the quality management systems may allow the firms to meet the legislative requirements, the goal of tighter inventory management has not been met by the majority of the firms. The narrowest confidence interval was noted in 2007, but the mean value of the traceability index was the highest of all three years' data. This indicates that 2007 was not a positive year for improvements in inventory management or traceability capabilities for the organization.

This specific case does show that the mock recall exercise can be used as an evaluation tool for both the recall procedure and for a quality management system focusing on traceability and inventory control. Two factors which play a role in the power of mock recall to assist in evaluation is the quality of the data and the number of exercises to evaluate. The data collected must be valid and usable and this quality level rests heavily on employee actions. If employees do not collect daily operations data appropriately, evaluation of the system using mock recall exercises is much more difficult, if not impossible. In addition, the greater the number of exercises to evaluate, the more opportunities the firm has for feedback and refinement of their mock recall procedures and their quality management system. Ultimately, greater improvement in these areas may lead to improvements in quality processes at the organizational level.

Although many firms find mock recall exercises to be an inconvenience, the evaluative potential of mock recalls will assist the firm in the event of an actual recall. Without rehearsal, organizations will find themselves unprepared. Many quality management systems include product traceability as a requirement, therefore, it is in the best interest of firms to follow through with mock recall to measure effectiveness, prepare for future events, and ensure continuous quality improvement.

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Appendix A – Mock Recall Procedure

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Procedure for Commodity Grain Recall:

The Grain Marketing Manager shall initiate the recall by calling the Location Manager. The notification of recall shall be made via telephone, and shall also be documented in writing and may be transmitted via FAX or e-mail. The recall notification shall include as much pertinent information as possible such as:

- Reason for the recall
- Customer name
- Date and scale ticket number (if known)
- Train ID number

The Location Manager shall lead the recall process, with the assistance of designated personnel, who are assigned responsibility for the following:

1. Locate and secure for future reference retained grain samples. If testing or grading procedures are available, conduct an initial examination to determine if reported problem can be identified in the sample.
2. Identify all bins that contributed to the loading of the train (if applicable).
3. Determine for each bin, a point in time when it was known that the contamination did not exist determined by (which ever is later):
 - a. Date of previous uncontaminated shipment from bin.
 - b. Date of bin being completely emptied.
4. Compile scale ticket identification of all receipts and in-house transfers put into bins from the point in time when no contamination was known to exist.
5. Compile a list, based on Scale Ticket identification, of dates and names of all possible origins of contaminated grain.
6. Compile a summary of the recall.
7. To assist in identifying the records normally associated with a recall, FC QMS Form, *Commodity Grain Recall Record Checklist* shall be filled out. The Location Manager shall compile a folder containing copies of applicable records which may include:
 - *Recall Notification* noting Train ID Number or Scale Ticket Number and issues necessitating the recall.
 - *Loading Order*
 - *Grading Comparison*
 - *Stock Transfer Report*
 - *Quality & Quantity Blending Spreadsheet* for train being recalled
 - *Quality & Quantity Blending Spreadsheet* for previously loaded trains (Any train loaded from bins associated with recall)
 - *In-house Bin Transfer Log*
 - *Empty Bin Sanitation Log*
 - *Bin Entry Permits*
 - *Scale Ticket Report* for all bins associated with recall
 - *Customer Position Report*
 - *Scale tickets* (If requested by Grain Marketing)
 - *Nonconforming Grain Report* (ISO 9001:2000 locations)
8. As soon as possible, the Commodity Grain Recall Report and documentation folder shall be delivered to, the Grain Marketing Manager at which time all information shall be reviewed.